DEC - 6 2000

K002798

510(k) Summary
for the CODMAN® CRANIOSORB™ Absorbable Fixation System Drill Bits

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

Contact Person

James M. Flaherty, Jr., RAC
Regulatory Affairs Specialist
Telephone Number: (508) 880-8404
Fax Number: (508) 828-3212

Name of Device

Proprietary Name:	CODMAN® CRANIOSORB™ Absorbable Fixation System Drill Bits
Common Name:	Craniofacial drill bits
Classification Name:	• Bone cutting instrument and accessories • Powered simple cranial drills, burrs, trephines, and their accessories

Device Classification

These devices have been placed in Class II for bone cutting instruments and accessories per 21 CFR § 872.4120 (DZI) and powered simple cranial drills, burrs, trephines, and their accessories per 21 CFR § 882.4310 (HBE).

Statement of Substantial Equivalence

The CODMAN® CRANIOSORB™ Absorbable Fixation System Drill Bits are substantially equivalent to the BIOPLATE® Neurosurgery Fixation System Drill Bits based on the subject devices' similarity to the predicate devices in intended use, materials, design, and principles of operation.

Indications for Use

The CODMAN® CRANIOSORB™ Absorbable Fixation System Drill Bits are intended for use with the CODMAN® CRANIOSORB™ Absorbable Fixation System to drill pilot holes through the holes in CRANIOSORB™ plates and meshes prior to rivet placement.

Physical Description

The CODMAN® CRANIOSORB™ Drill Bits are comprised of a metal drill bit and spring-loaded drill housing. The drill housing, which is designed to mate with CRANIOSORB™ Plates and Meshes, operates as a self-centering drill guide as well as a drill stop. The CRANIOSORB™ Drill Bits are offered in two lengths (3mm and 5mm) to match the CRANIOSORB™ Rivet size used, and multiple drill bits are offered for use with various power drill systems. All patient contacting components are constructed from fully biocompatible materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2000

Mr. James M. Flaherty
Regulatory Affairs Specialist
Codman & Shurtleff, Incorporated
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K002798
Trade Name: Codman Craniosorb Absorbable Fixation System Drill Bits
Regulatory Class: II
Product Code: JEY
Dated: September 6, 2000
Received: September 7, 2000

Dear Mr. Flaherty:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucinotta for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K002798

Device Name **CODMAN® CRANIOSORB™ Absorbable Fixation System Drill Bits**

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(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR §801.109)

(Optional Format 1-2-96)

Rebecca Cucuzza

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002798